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June 24, 2021

VIA ECF

Hon. Douglas E. Arpert, U.S.M.J.
United States District Court for the District of New Jersey
Clarkson S. Fisher Federal Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: *Catalyst Pharmaceuticals, Inc., et al. v. Jacobus Pharmaceuticals, Inc.*
Civil Action No.: 3:20-cv-14590 (MAS-DEA) (consolidated)

Dear Judge Arpert:

This firm, together with Sterne, Kessler, Goldstein & Fox PLLC, represents Plaintiffs Catalyst Pharmaceuticals, Inc. and SERB SA. (collectively, "Plaintiffs") in the above-captioned consolidated matter. Pursuant to the Discovery Confidentiality Order ("DCO") entered in this case (Dkt 51), Plaintiffs object to the disclosure of Highly Confidential information to Dr. Vern C. Juel. The parties have met and conferred and have been unable to reach resolution on this issue. Plaintiffs requested more information about Dr. Juel's ongoing responsibilities with Defendant Jacobus Pharmaceutical Company, Inc. ("Jacobus") in an attempt to modify or withdraw its objection, but Defendant refused to provide same. Accordingly, Plaintiffs' submit this letter, in accordance with the DCO, to seek the Court's assistance in resolving the issue.

Defendants disclosed that Dr. Juel "served as an investigator in connection with Jacobus Pharmaceutical Company, Inc. products and is an IND-holder for Jacobus' compassionate-use program for 3,4-diaminopyridine." Exhibit A at 1. However, Dr. Juel's connection with Jacobus appears to be more involved than just an outside investigator and IND holder. Plaintiffs have independently learned that Dr. Juel received at least \$100,000 for "research" as of 2015, but could not discover whether he received any additional payments after 2015. Exhibit B at 2. Moreover, Dr. Juel was not only just an "investigator" – he was the principal investigator for Jacobus in its development of Ruzurgi—the accused product in this case and also a direct competitor to Plaintiffs' flagship product, Firdapse—and is listed as an author on multiple papers describing Jacobus's clinical trials for Ruzurgi and 3,4-DAP.¹ Exhibit C at 6, 7, 12, 19. Based on these connections, Dr. Juel appears to have significant ties to Jacobus's business and clinical program relating to 3,4-DAP, which render him tantamount to an in-house employee rather than an independent outside contractor. Defendants have refused to provide additional information regarding the full extent of Dr. Juel's ties to Jacobus and his ongoing involvement with Jacobus.

Plaintiffs met and conferred with Defendants on this issue on June 18, 2021 to get additional information about Dr. Juel and to attempt to resolve the issue without the Court's intervention. Exhibit D at 1. Plaintiffs explained that they would be willing to drop the objection to Dr. Juel if Defendants could represent that Dr. Juel was no longer involved with Jacobus other

¹ Separately, Plaintiffs are considering whether to depose Dr. Juel as a fact witness.

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than for purposes of this litigation, and going forward would not engage in the type of activities that he has performed in the past that gives rise to Plaintiffs' concerns. Defendants refused to make that representation. Plaintiffs then stated they would reconsider their objection if Defendants would provide more detail as to what services Dr. Juel provides to Jacobus. Defendants did not provide this information. Defendants' refusal to explain Dr. Juel's activities with respect to Jacobus reinforces Plaintiffs' concerns about the potential for inadvertent use.

Dr. Juel should not be permitted to have access to Plaintiffs' information marked "Highly Confidential" because his extensive involvement with Jacobus makes him the equivalent of an in-house employee of Jacobus. The DCO bars the disclosure of Highly Confidential information to in-house employees. Dkt 51 at ¶ 9. The disclosure of Catalyst's Highly Confidential information, particularly related to 3,4-DAP, future clinical studies, and other research and development, would cause irreparable harm as Dr. Juel may inadvertently use the information on behalf of Jacobus for purposes unconnected to this litigation. This is precisely the type of scenario that the DCO is designed to prevent.

The disclosure of Catalyst's Highly Confidential information to Dr. Juel poses a serious threat of irreparable harm to Catalyst, as Catalyst and Jacobus market similar drug products – 3,4-DAP. Catalyst is a pharmaceutical company engaged in the research, development, and marketing of 3,4-DAP products. While it has FDA approval for the treatment of 3,4-DAP, it is currently engaged in clinical development for the use of 3,4-DAP to treat spinal muscular atrophy and downbeat nystagmus. See <https://catalystpharma.com/pipeline-clinical/>. Jacobus is a pharmaceutical company that markets 3,4-DAP for the treatment of LEMs. Catalyst considers Jacobus a direct competitor, as both market 3,4-DAP for the treatment of LEMs.²

Plaintiffs have already produced over 25,000 Highly Confidential documents to Defendants. These documents include the research, development, and clinical development of applications of 3,4-DAP, such as the use of 3,4-DAP to treat spinal muscular atrophy and downbeat nystagmus. If Defendants are permitted to disclose this information to Dr. Juel, he will learn the details of Catalyst's development efforts. Just as the parties recognized that the risk of inadvertent disclosure warranted a patent prosecution bar, so too should the risk of inadvertent use of Catalyst's research and development documents warrant a bar against disclosure to an individual involved in research and development at Jacobus.

The inadvertent use of Catalyst's Highly Confidential information would cause precisely the type of irreparable harm that the DCO was intended to avoid. The DCO allows any number of independent outside experts to review Confidential Information, Highly Confidential information, Confidential Health information. In contrast, only two in-house representatives from each party are permitted to view Confidential Information. They are restricted from receiving Highly Confidential information and Confidential Health Information. In this way, the risk of irreparable harm from the inadvertent use of a party's trade secrets is minimized. But, the risk of irreparable harm is no longer mitigated as the DCO intends if a party can designate an individual who has ongoing responsibilities such that he is more akin to an in-house employee than an independent expert; that is precisely the situation with Dr. Juel. Accordingly, Plaintiffs respectfully request that Defendants be prohibited from sharing Plaintiffs' Highly Confidential information with Dr. Juel.

We are available should Your Honor have any questions and we appreciate the Court's attention to these matters.

² Catalyst's product, Firdapse, is indicated for the adult population. Jacobus's product, Ruzurgi, is indicated for the pediatric population.

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Respectfully submitted,

s/Liza M. Walsh

Liza M. Walsh

Encl.

cc: All Counsel of Record (via ECF & email)